Joshua B. Silverman
Louis C. Ludwig
Christopher P.T. Tourek
POMERANTZ LLP
10 South LaSalle St., Ste. 3505
Chicago, Illinois 60603
Telephone: (312) 377-1181
Facsimile: (312) 377-1184
jbsilverman@pomlaw.com
lcludwig@pomlaw.com
ctourek@pomlaw.com

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ADAM PAXTON, Individually and On Behalf of All Others Similarly Situated, Plaintiffs, v. PROVENTION BIO, INC., ASHLEIGH PALMER, and ANDREW DRECHSLER, Defendants.	Case No. 3:21-cv-11613-MAS-TJB **CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS** Judge Michael A. Shipp Mag. Tonianne J. Bongiovanni JURY TRIAL DEMANDED

Lead Plaintiff George L. Jordan, Jr. and additional named Plaintiff Adam Paxton ("Plaintiffs"), individually and on behalf of all others similarly situated, by their undersigned attorneys, for Plaintiffs' amended complaint against Defendants, allege the following based upon personal knowledge as to Plaintiffs and Plaintiffs' own acts, and information and belief as to all other matters, based upon, *inter alia*,

the investigation conducted by and through Plaintiffs' attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, briefing documents and transcripts published by the United States Food and Drug Administration ("FDA"), analysts' reports and advisories about Provention Bio, Inc. ("Provention" or the "Company"), and information obtained from interviews with knowledgeable former employees of the Company. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

INTRODUCTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Provention securities between November 2, 2020 and July 6, 2021, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Provention is a clinical-stage biopharmaceutical company whose product candidates include PRV-031 teplizumab and monoclonal antibodies ("mAb"), in Phase III clinical trial for the interception of Type One Diabetes

("T1D").

3. Provention acquired the rights to teplizumab from MacroGenics after another drug company, Eli Lilly, abandoned its development of the treatment.

4. The FDA granted Breakthrough Therapy Designation for teplizumab in August 2019. Breakthrough Therapy Designation does not lower the standards for approval, but does allow a greater degree of interaction with the FDA as well as the ability to submit a BLA on a rolling basis and obtain Priority Review. Provention took advantage of these procedures and requested a Priority Review, which had potential to shorten the time for action on the application to 6 months instead of the standard 10 months.

5. Ashleigh Palmer, Provention's CEO, stated that "[o]ur submission of the final modules of the rolling BLA represents a significant milestone for Provention Bio and a critical step toward the potential first major advancement in T1D therapeutics since insulin was introduced a century ago."

6. In early November 2020, Provention completed the rolling submission of a Biologics License Application ("BLA") to the FDA for teplizumab for the delay or prevention of clinical T1D in at-risk individuals (the "teplizumab BLA").

7. Throughout the Class Period, Defendants touted teplizumab and omitted critical flaws about their clinical trials. As a result, Provention's stock was

artificially inflated, allowing Defendants to dump 600,000 shares of stock at windfall prices.

8. Defendants' misleading statements regarding the teplizumab BLA's prospects misrepresented or omitted (i) the small size of the study which the teplizumab BLA was predicated upon; (ii) the fact that patients enrolled in that same study were not followed after their diabetes diagnosis; and (iii) most critically, Defendants could not show equivalence between Provention's product intended for commercial sale, and the drug that teplizumab's original developer, Eli Lilly used in clinical trials.

9. To make matters worse, Provention concealed the fact that its manufacturing facilities for teplizumab were deficient.

10. As a result of the above deficiencies and others disclosed in the briefing documents for and testimony at the FDA's May 27, 2021 Advisory Committee Meeting, the teplizumab BLA remains mired in regulatory uncertainty, and has yet to receive FDA approval.

11. As a result of Defendants' wrongful acts and omissions, Plaintiffs and other Class members suffered significant losses and damages.

12. In January 2021, after Defendants revealed problems in a "Bridging Study" meant to demonstrate the similarities between teplizumab and an older

iteration, Provention stock dropped by $2.79, or 14.34%, from $19.45 on January 12, 2021 to close at $16.66 on January 13, 2021.

13. In February 2021, following fresh revelations about the Bridging Study and its impact on the teplizumab BLA, Provention's stock price dropped by $1.82, or 12.42%, from $14.65 on February 24, 2021 to close at $12.83 on February 25, 2021.

14. Subsequently, after Defendants hinted at the non-comparability between their teplizumab and Eli Lilly's, Provention's stock price fell $1.73 per share, or 17.78%, from $9.73 on April 8, 2021 to close at $8.00 per share on April 9, 2021.

15. Then, after Defendants told the market that the BLA was in jeopardy, Provention's stock price fell $0.43 per share, or 6.02%, from $7.14 on May 7, 2021 to close at $6.71 per share on May 10, 2021.

16. In late May 2021, after the Advisory Committee meeting – which analysts expected, based on Defendants' false and misleading statements, to conclude in a unanimous vote of approval – went sideways, Provention's stock price fell $3.07 per share, or 28.74%, from $10.68 on May 27, 2021 to close at $7.61 per share on May 28, 2021.

17. Finally, after Defendants received a rejection letter from the FDA, Provention shares dropped $2.19 per share, or 26.38%, from $8.30 on July 2, 2021

to close at $6.11 per share on July 6, 2021, and again fell $0.12 per share, or 1.96%, to close at $5.99 per share on July 7, 2021.

18. At present, the stock trades for less than $7 per share.

JURISDICTION AND VENUE

19. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

20. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

21. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Provention is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

22. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mail, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

23. Plaintiffs purchased Provention common stock at artificially inflated

prices during the Class Period, as set forth in their certifications previously filed with the Court and incorporated herein by reference, and were damaged thereby, upon the revelation of the alleged corrective disclosures.

24. Defendant Provention is a Delaware corporation with principal executive offices located at 55 Broad Street, 2nd Floor, Red Bank, New Jersey 07701. The Company's common stock trades in an efficient market on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol "PRVB."

25. Defendant Ashleigh Palmer ("Palmer") is the founder of Provention and has served as its Chief Executive Officer ("CEO") at all relevant times. Palmer has over thirty (30) years of experience in corporate strategy/transactions, preclinical/clinical drug evaluation, and product development/commercialization. Palmer has served as CEO for multiple biopharmaceutical companies and, as a result, has extensive experience dealing with the FDA.

26. Defendant Andrew Drechsler ("Drechsler") has served as Provention's Chief Financial Officer ("CFO") at all relevant times. Drechsler has over twenty-five (25) years of experience in the financial and life-sciences industry, and has acted as the CFO for multiple pharmaceutical companies, including Insmed, Inc. and Valera Pharmaceuticals.

27. Defendants Palmer and Drechsler are sometimes referred to herein collectively as the "Individual Defendants."

28. The Individual Defendants possessed the power and authority to control the contents of Provention's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Provention's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Provention, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

29. Provention and the Individual Defendants are collectively referred to herein as "Defendants."

FACTUAL BACKGROUND

I. The FDA's Biologics License Application Process

30. In the United States, pharmaceutical development and marketing is regulated by the FDA, an agency of the U.S. Department of Health and Human Services. The modern regulatory regime was enacted in 1962, after Thalidomide, a sleeping and anti-morning sickness pill, caused birth defects in thousands of babies.

In reaction to this tragedy, Congress passed the Kefauver-Harris Amendments to the Food, Drug and Cosmetic Act (the "FDCA") requiring that any company that wanted to market a pharmaceutical product in the United States (in industry parlance, a "sponsor") had to obtain prior approval from the FDA and that the approval had to be based upon substantial scientific evidence demonstrating that the product was safe and effective for its intended use in humans.

31. The FDCA, as amended, requires the Commissioner of the FDA to refuse any drug application if:

- "he has insufficient information to determine whether such drug is safe for use under such conditions;" or
- "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof."

21 U.S.C. § 355(d)(4)-(5).

32. The FDA is only permitted to consider clinical evidence to be "substantial," and thus satisfy the FDCA, if it:

> consist[s] of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

21 U.S.C. § 355(d). Well-controlled clinical investigations measure the subject drug against a control group, which is provided either a placebo or another already approved drug for comparison.

33. These FDA guidelines apply to several different applications, including a BLA, which is a request for permission to introduce a biologic product into interstate commerce.[1]

34. A BLA is submitted by any entity who is engaged in the manufacture or an applicant for a license who takes responsibility for compliance with product and establishment standards, and attests that a product is safe, pure, and potent, that the manufacturing facilities are inspectable, and that each package of the product bears the license number.

35. Teplizumab is a novel biologic and therefore subject to two relevant considerations for FDA approval: 1) general approval standards and 2) comparability standards.

36. For novel biologics like teplizumab, general approval standards are covered under section 42 U.S.C. § 262 is (a)(2)(C), which reads:

(C) The Secretary shall approve a biologics license application—

(i) on the basis of a demonstration that—

[1] *See, generally, Biologics License Applications (BLA) Process (CBER)*, U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber (last accessed Dec. 20, 2021).

> (I) the biological product that is the subject of the application is safe, pure, and potent; and
>
> (II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and
>
> (ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

37. Where, as here, a study submitted in support of a BLA used a different manufacturer or different manufacturing process from the drug candidate for which licensing is sought in the BLA, the sponsor must show that the two study drug and the drug candidate are biocomparable. As Provention ultimately admitted near the end of the Class Period, *see* ¶130, *infra*, Provention "pre-specified" that comparability would be assessed by the traditional measure employed by the FDA: determining whether the 90% confidence interval of the log-transformed area-under-the-curve ("AUC") exposure measure between the two drugs fell within the range of 80%-125%.

38. When submitting a BLA, the sponsor, not the FDA, is responsible for determining the design of clinical trials and the protocols for each trial. If a sponsor wants the FDA to agree that a particular trial or trials is sufficient for approval in the

event that endpoints are met, the sponsor may request a Special Protocol Assessment pursuant to 21 U.S.C. § 355(b)(5)(C). Under this provision, the FDA and sponsor meet to discuss the sponsor's proposed protocols, and reduce any agreements in writing with the resulting documents becoming part of the administrative record. Such agreements may not be changed except by mutual consent or under exceptional medical or scientific circumstances. *Id.*

39. Sponsors of a BLA are also responsible for enrolling patients in clinical trials. Enrollment can be a lengthy and expensive part of a clinical trial, especially in a larger trial, a trial for a rare disease, or a trial in a field with other competing studies. Regardless of where patients are enrolled, a sponsor must ensure that the trial is conducted according to protocol, and must demonstrate benefit to the patient population for which approval is sought.

40. A sponsor generally conducts clinical trials in three phases. These phases, which are codified in FDA regulations, are as follows:

A. Phase 1. Phase 1 studies "are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness."

B. Phase 2. Phase 2 studies are "typically well controlled" studies "conducted to evaluate the effectiveness of the drug for a particular

indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug."

C. Phase 3. Phase 3 studies are expanded studies "performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects."

21 C.F.R. § 312.21. Those studies which a sponsor uses to support approval from the FDA are known as "pivotal" clinical trials.

41. When a sponsor believes it has conducted sufficient well-controlled clinical trials and believes that those trials demonstrate substantial evidence of efficacy and safety consistent with the FDCA, the sponsor may prepare and file a BLA with the FDA seeking approval to market the subject drug in a specific dose for the treatment of a specific condition or "indication." The BLA must also specify how the drug will be manufactured, packaged, and labeled. The FDA can only grant approval when presented with scientific evidence meeting the requisite statutory criteria.

42. Within sixty (60) days of receiving an BLA, the FDA will accept the BLA for filing if it believes there is sufficiently complete information to permit a substantive review of the information contained within the BLA. The acceptance of a BLA for filing is not a determination of the substantive merits of the BLA, but rather a threshold determination of whether there is enough data to conduct a substantive examination. If the FDA determines that there is a facial problem preventing a meaningful substantive examination – for example, if the BLA is missing paperwork, fails to include data in the proper format, or suffers from other facial errors that make review impossible – the FDA may refuse to file the BLA.

43. The filing of a BLA triggers review deadlines specified in the Prescription Drug User Fee Act ("PDUFA"), enacted in 1992 and reauthorized by amendment every five years thereafter. Under the PDUFA, the FDA is generally required to respond to the BLA within six months. The date by which the FDA must issue its response is frequently referred to as a drug's "PDUFA date." Under PDUFA, the FDA is will, in most cases, issue a decision within ten (10) months for standard review applications and within six (6) months for priority review applications. The date by which the FDA must issue its response is frequently referred to as a drug's "PDUFA date."

44. A BLA accepted for filing is reviewed for substance by the FDA's Center for Drug Evaluation & Research ("CDER"). Prior to the PDUFA date,

CDER may (or may not) convene an advisory committee to provide it with technical advice, enhance its decision-making process, and provide a forum for public discussion of controversial issues.

45. If an advisory committee is convened, the sponsor and FDA staff will each provide the advisory committee briefing documents and make presentations to the advisory committee. After receiving the submissions of both the sponsor and the FDA, and hearing their respective presentations, the advisory committee will discuss the safety and efficacy of the drug candidate and provide the FDA with a nonbinding vote on specific questions regarding safety and efficacy, and whether approval is warranted based upon the evidence of safety and efficacy provided by the sponsor.

46. Critically, an advisory committee is the only forum in which the public can legally be advised by the FDA of the FDA's position and the FDA's interactions with the sponsor regarding the drug candidate. Except in advisory committee briefing documents and during the advisory committee hearing, FDA secrecy regulations strictly prohibit the agency from disclosing information regarding pending BLAs. As a result, without an advisory committee, the FDA may not publicly refute a sponsor's misrepresentations regarding clinical trials, protocols, or the sponsor's interactions with the FDA, no matter how false or misleading those statements may be. *See* 21 C.F.R. § 314.430. And, in fact, research by the FDA has found that sponsors routinely fail to accurately describe the content of

communications with the agency in their public-facing disclosures.[2]

47. If the FDA, after reviewing all of the pertinent information, decides not to approve a BLA, it then notifies the sponsor via a Complete Response Letter ("CRL"), which includes the deficiencies found by the review team and recommendations for corrective action. The CRL is not published, but instead delivered only to the entity sponsoring the BLA.

II. Provention Bio, T1D, & Teplizumab

48. Provention – founded in 2016 by Palmer and Francisco Leon – purports to focus on the development and commercialization of therapeutics and solutions to intercept and prevent immune-mediated diseases.

49. In May 2018, Provention acquired teplizumab from MacroGenics, and subsequently entered into a contract with AGC Biologics in February 2019 to out of its facilities in Seattle, Washington for subsequent clinical and commercial use. Shortly after Provention's acquisition, teplizumab became the central focus of Provention's efforts to develop a drug that combats T1D.

50. T1D is an autoimmune disease caused by T-cell mediated autoimmune destruction of the pancreatic beta cells. The resulting loss of pancreatic beta cells

[2] *See generally* Peter Lurie, Harinder S Chahal, Daniel W Sigelman, Sylvie Stacy, Joshua Sclar, Barbara Ddamulira, *Comparison of Content of FDA Letters Not Approving Applications For New Drugs and Associated Public Announcements From Sponsors: Cross Sectional Study*, THE BMJ April 8, 2015, https://www.bmj.com/content/350/bmj.h2758 (last accessed Dec. 23, 2021).

leads to impaired insulin production and secretion, and impaired glucose metabolism. Persons with T1D are at greater risk for serious cardiovascular outcomes than the general population, due to a lifelong increased glycemic load, resulting in a decreased life expectancy. T1D also increases the risk for secondary end-organ complications, including visual impairment and blindness, renal failure, vascular disease and limb amputation, peripheral neuropathy, and stroke.

51. T1D has three stages:

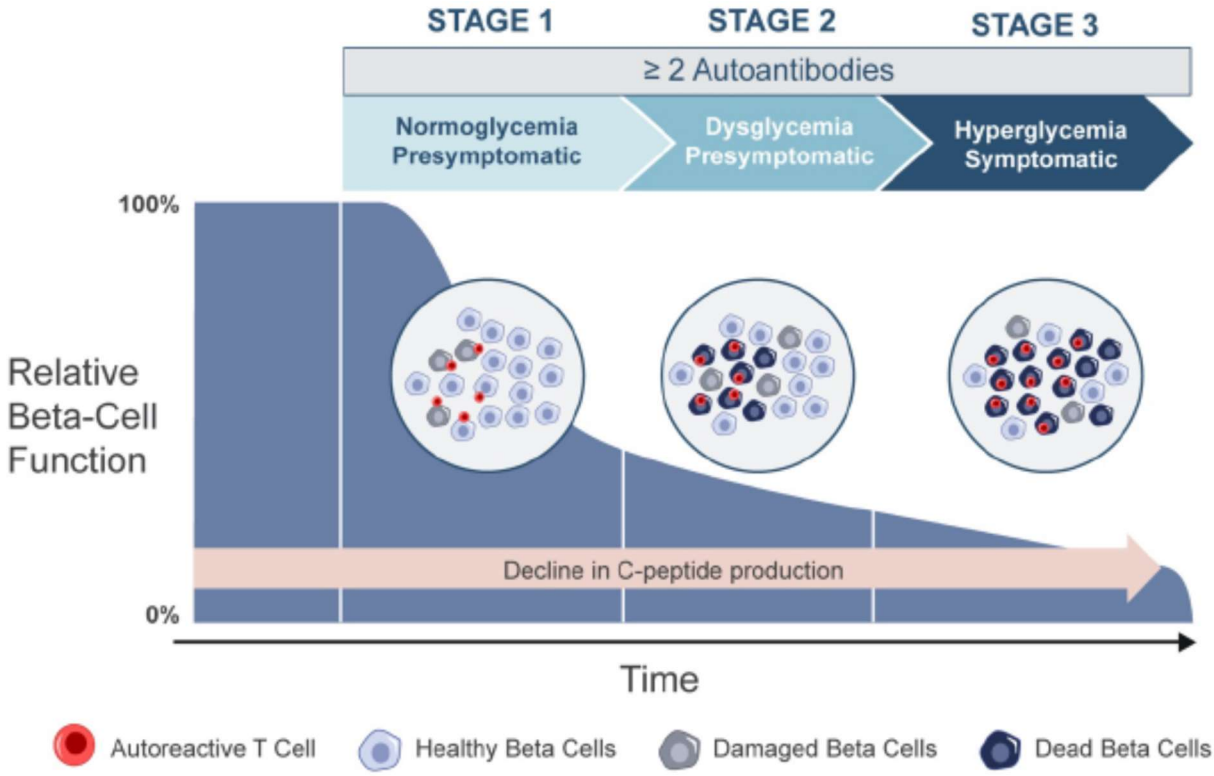
A. Stage 1: the asymptomatic stage with the emergence of 2 or more T1D-related autoantibodies, which reflect the initiation of the autoimmune process, and normoglycemia. At this stage, there is a 44% risk of progression to Stage 3 in five (5) years and the lifetime risk approaches 100%.

B. Stage 2: the pre-symptomatic stage with the persistence of 2 or more T1D-related autoantibodies with further loss of beta cell function and development of dysglycemia. At this stage, there is a 75% risk of progression to Stage 3 in 5 years and the lifetime risk approaches 100%.

C. Stage 3: the symptomatic stage, or clinical T1D, where the remaining beta cell capacity is insufficient to maintain glucose control and exogenous insulin is needed.

52. As outlined by the chart below, as the beta cell capacity and C-peptide

production decreases, patients progress to Stage 2 and ultimately Stage 3 T1D[3]:



53. There is currently no known treatment for Stage 1 and 2 T1D. However, once a patient has Stage 3 T1D, they are treated through insulin therapy, which consists of frequent daily insulin injections. Insulin therapy, however, has several unwanted side effects such as weight gain and hypoglycemia, as well as the burden of frequent daily insulin injections and blood glucose self-monitoring. Even with insulin therapy, desired glycemic targets are not achieved in most patients.

54. Approximately 1.5 million Americans have T1D, and it is the second-most common chronic disease of childhood.

[3] Chart obtained from Provention's Sponsor Briefing Document to the FDA Advisory Committee, p. 26.

55. Teplizumab is an anti-CD3 monoclonal antibody that was originally developed at the University of Chicago in partnership with Ortho Pharmaceuticals.

56. In 2005, based on promising C-peptide preservation data, teplizumab was acquired by MacroGenics, Inc. ("MacroGenics") who, in partnership with Eli Lilly, conducted the first Phase 3 clinical trial in early-onset T1D. Eli Lilly manufactured teplizumab out of its facilities in Ireland for the clinical trials. The clinical trial consisted of three studies: Protégé, Protégé Extension, and Encore. MacroGenics' primarily focused on delaying disease progression (loss of beta cell function as measured by C-peptide levels) in newly diagnosed Stage 3 T1D patients. In 2010, MacroGenics announced that its Phase 3 clinical trial failed to demonstrate that teplizumab would be effective in treating patients with early-onset clinical Stage 3 T1D, and it was halting its partnership with Eli Lilly and discontinued any further clinical development of the drug on its part.

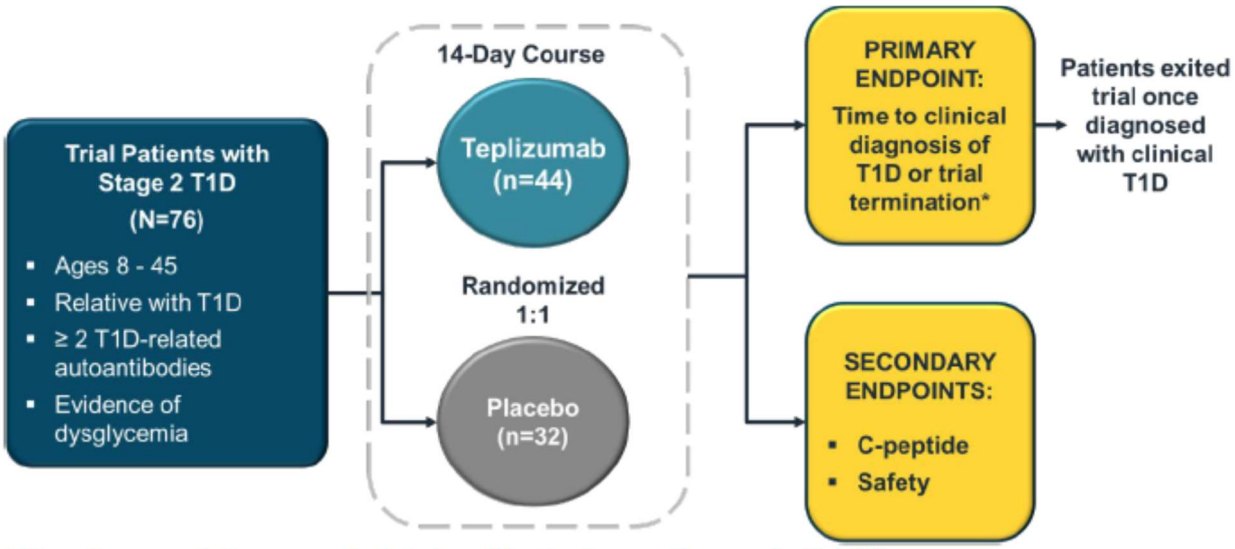
III. The Pivotal TN-10 Study

57. In 2011, notwithstanding MacroGenics' halting of all further clinical trials, a randomized, placebo-controlled study was initiated by the National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK") and TrialNet, an international network of academic institutions dedicated to the prevention and early treatment of T1D, to evaluate the effect of teplizumab in at-risk Stage 2 T1D

patients, defined as those with at least two T1D-related autoantibodies and dysglycemia (the "TN-10 study").

58. Significantly, while MacroGenics' research was focused on the treatment of clinical Stage 3 T1D patients, the TN-10 study focused on whether teplizumab could be used to delay or prevent clinical Stage 3 T1D in patients who have Stage 2 T1D.

59. The TN-10 study was designed as a multicenter, double-blind, randomized (1:1), placebo-controlled study to determine whether treatment with teplizumab in patients at high risk for diabetes resulted in delay or prevention of clinical Stage 3 T1D[4]:



[4] Chart obtained from Provention's Sponsor Briefing Document to the FDA Advisory Committee, p. 42.

60. Significantly, the original 2010 protocol, which called for the enrollment of 144 at-risk patients, was revised by TrialNet in 2014 (due to slower-than-expected enrollment rates) to reduce the sample size to 71 at-risk patients and to follow patients until 40 were diagnosed with T1D.

61. In November 2018, TrialNet conducted a primary analysis of the TN-10 study. On June 9, 2019, TrialNet announced the results of its analysis and stated that the primary endpoint was met and that a single 14-day course of teplizumab in patients with Stage 2 T1D significantly delayed the median onset of clinical Stage 3 T1D by a minimum of two years compared to the placebo. Moreover, the TN-10 study found that more patients who took teplizumab remained free of clinical Stage 3 T1D beyond five years compared to patients who took the placebo.

62. At the time of TrialNet's analysis, 54.5% of patients who took teplizumab remained free of clinical Stage 3 T1D, whereas 28.2% of patients who took the placebo remained free of clinical Stage 3 T1D.

63. TrialNet also announced that the analysis of the secondary endpoint in the TN-10 study demonstrated that teplizumab had a statistically significant effect on preserving beta cell function as measured by C-peptide AUC levels.

64. In August 2019, based upon these results, Provention applied for and was granted a Breakthrough Therapy designation for teplizumab in Stage 2 T1D patients. A "Breakthrough Therapy" designation is a designation requested by a drug

company that expedites "the development and FDA review of drugs, and is only given to potential drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s)."[5] A drug that receives Breakthrough Therapy designation is eligible for (a) Fast Track designation; (b) intensive guidance on an efficient drug development program, beginning as early as Phase 1; and (c) organizational commitment involving senior managers.

IV. Provention's Biologics License Application Process & Bridging Study

65. On April 16, 2020, Provention issued a press release announcing the start of its rolling submission of the teplizumab BLA to the FDA. The press release cited Palmer, who stated:

> The initiation of our BLA submission process represents an important milestone for Provention as we advance teplizumab toward the market as the first-ever treatment for patients at-risk of advancing to clinical type 1 diabetes … The data from the [TN-10 study], published last year, underscores the transformative therapeutic potential of teplizumab to delay or prevent the onset of clinical-stage, insulin-dependent, T1D. We remain on track to complete the BLA submission by year-end and look forward to working with the FDA as we advance the regulatory process.

[5] *Breakthrough Therapy*, U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy (accessed Oct. 15, 2021).

66. Part of Provention's BLA for teplizumab was clinical data based on teplizumab manufactured by Eli Lilly (the "Lilly-teplizumab"). Because Provention's teplizumab was produced by AGC Biologics in Seattle, Washington, as opposed to by Eli Lilly in Ireland, Provention needed to demonstrate that the clinical data of the Lilly-teplizumab was applicable to its version of teplizumab (the "PRVB-teplizumab") in order to satisfy 42 U.S.C. § 262(k)(2)(A)(i)(I)-(V).

67. To do this, Provention conducted a single study to demonstrate that the pharmacokinetic ("PK") and pharmacodynamic ("PD") data support a demonstration of biosimilarity (the "Bridging Study"). Pharmacokinetics refers to the "activity of drugs in the body over a period of time, including the process by which drugs are absorbed, distributed in the body, localized in the tissues, and excreted."[6] Pharmacodynamics refers to how the body reacts to a drug.[7]

68. To demonstrate that a drug is biocomparable with another drug, it must show that it has a similar PK AUC. In the field of pharmacokinetics, the AUC reflects the actual body exposure to a drug after the administration of a dose.[8]

---

[6] *Pharmacokinetics*, Nat'l Cancer Inst., https://www.cancer.gov/publications/dictionaries/cancer-terms/def/pharmacokinetics (last accessed Oct. 15, 2021).

[7] Mark Marino, Zohaib Jamal, & Patrick M. Zito, *Pharmacodynamics*, Nat'l Ctr. For Biotechnology Info., Feb. 10, 2021, https://www.ncbi.nlm.nih.gov/books/NBK507791/.

[8] Jeremy D. Scheff, Richard R. Almon, Debra C. DuBois, William J. Jusko, & Ioannis P. Androulakis, *Assessment of Pharmacologic Area Under the Curve When Vaselines are Variable*, PHARMACEUTICAL RESEARCH, Jan. 14, 2011, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3152796/.

69. Provention pre-specified that comparability of the two different versions of teplizumab would be assessed using the traditional FDA measure of considering whether the ratio of PK AUC between the two drugs fell within the range of 80%-125%.[9] Essentially, to find biocomparability, a study must find that a drug has a similar lasting impact on a patient's body in both time and effect as another drug.

70. While Defendants cited the 80-125% range in the public statements during the Class Period, the teplizumab BLA was *not* an NDA. Accordingly, the 80-125% standard was inapplicable, and Defendants were required to show "[a]dequate pharmacokinetics measurements may include determination of Cmax, Tmax, AUC and t ½ in either parallel or cross-over study designs."[10]

71. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/demonstration-comparability-human-biological-products-including-therapeutic-biotechnology-derived

72. Provention purported to assess PK and PD in a study it called the "Bridging Study." The Bridging Study was a single low-dose biocomparability

[9] *Guidance for Industry*, U.S. FOOD & DRUG ADMINISTRATION, at 26, https://www.fda.gov/files/drugs/published/Bioavailability-and-Bioequivalence-Studies-Submitted-in-NDAs-or-INDs-%E2%80%94-General-Considerations.pdf (last accessed Oct. 15, 2021).

[10] *See* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/demonstration-comparability-human-biological-products-including-therapeutic-biotechnology-derived (last accessed Dec. 23, 2021).

study in healthy volunteers. Significantly, the Bridging Study was the first time that PRVB-teplizumab was ever used in humans.

DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND OMISSIONS

V. Provention Completes the Rolling Submission of its BLA

73. As Provention completed its BLA, Defendants went on a concerted campaign to promote its efforts and teplizumab, all while omitting serious risks to and known defects with its application.

74. On November 2, 2020, Provention announced via a press release "the completion of the rolling submission of a [BLA] to the [FDA] for teplizumab for the delay or prevention of clinical [T1D] in at-risk individuals with the submission of the chemistry, manufacturing and controls (CMC) and administrative information modules." In connection with its completion of teplizumab's BLA, Provention announced that it had requested a "Priority Review" designation, which means that the FDA's goal is to take action on an application within 6 months (as opposed to 10 months under standard review). A Priority Review designation is meant to "direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the

treatment, diagnosis, or prevention of serious conditions when compared to standard applications."[11]

75. The November 2, 2020 press release stated, in relevant part: [12]

> "***Our submission of the final modules of the rolling BLA represents a significant milestone for Provention Bio and a critical step toward the potential first major advancement in T1D therapeutics since insulin was introduced a century ago***," stated Ashleigh Palmer, CEO and Co-Founder, Provention Bio. "We are extremely grateful to the entire Provention team and our key clinical, regulatory and manufacturing partners, as we could not have achieved this goal without their tireless dedication and determination. ***We look forward to continuing on our path toward changing the current treatment paradigm for T1D and, if approved, bringing teplizumab, designated by the FDA as a Breakthrough Therapy, to the U.S. market in 2021***."

76. The statements identified in Paragraph 75 were materially false and misleading when made because the statements omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) there was significant risk that Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the teplizumab BLA; (ii) Provention's pivotal study did not meet the enrollment specified in the original protocol and only ended

[11] *Priority Review*, U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review (last accessed Oct. 15, 2021).

[12] Emphasis added throughout, unless otherwise noted.

up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol; (iii) the safety data for teplizumab was insufficient because it was unclear what happened to study participants who got Type 1 diabetes after being treated; (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (v) Provention's manufacturing facilities for teplizumab were deficient; (vi) consequently, the teplizumab BLA was deficient in its submitted form and would require additional data to meet the standards for secure FDA approval; (vii) the teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed; and (viii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

77. The stock market took note of Provention's announcement, and in a three-day span, Provention's stock price jumped by $2.24, or 18.88%, from $11.86 on October 30, 3030 to close at $14.10 on November 4, 2020.

78. On November 5, 2020, Provention issued a press release announcing the Company's Q3 2020 financial results and providing a business update. The press release stated, in relevant part:

> "We are excited about the progress the Provention Bio team has made in recent months ***as we work to redefine the treatment landscape for T1D and other autoimmune diseases***," stated Ashleigh Palmer, CEO, Provention Bio. "***Earlier this week, we announced our achievement***

> ***of a major milestone with the completion of the rolling BLA submission for teplizumab for the delay or prevention of clinical T1D in at-risk individuals. In parallel with our regulatory efforts, we are focused on preparing for a potential product approval and launch in mid-2021***. . . .["]

79. The statements identified in Paragraph 78 were materially false and misleading when made because the statements omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) there was significant risk that Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the teplizumab BLA; (ii) Provention's pivotal study did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol; (iii) the safety data for teplizumab was insufficient because it was unclear what happened to study participants who got Type 1 diabetes after being treated; (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (v) Provention's manufacturing facilities for teplizumab were deficient; (vi) consequently, the teplizumab BLA was deficient in its submitted form and would require additional data to meet the standards for secure FDA approval; (vii) the teplizumab BLA lacked the evidentiary support the Company had

led investors to believe it possessed; and (viii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

80. That same day, Provention hosted an earnings call with investors and analysts to discuss the Company's Q3 2020 results (the "Q3 2020 Earnings Call"). During the scripted portion of the Q3 2020 Earnings Call, Palmer touted the Company's "***positive manufacturing progress"*** and stated, in relevant part:

> ***Data from th[e] [pivotal] study, which were included in the clinical module of our BLA submission showed that a single course of teplizumab consisting of a daily 30 to 60 minute infusion over two weeks significantly delayed the onset of insulin dependent Type 1 diabetes in pre-symptomatic patients by a median of approximately two years as compared to placebo.***
>
> ***More recently at this year's ADA Scientific Sessions in June, TN10 study follow-on data were presented showing the original 14-day course of teplizumab investigational therapy continued to significantly delay the onset of T1D in study participants by a median of approximately three years compared to placebo adding one more year to the previous two-year median delay.***
>
> ***There were even some patients receiving teplizumab who were still T1D free after 8.5 years. Not only are these results of the TN10 study highly statistically significant with a p- value of 0.006 tied to the original two-year median delay, they are also highly clinically relevant.***
>
> ***As such one of the advantages afforded to us under breakthrough therapy designation was the opportunity to submit our BLA on a rolling date.*** Earlier this year in April, we announced that we have successfully initiated this process by submitting the BLAs nonclinical module and this was then followed by our submission of the clinical module in September.

81. Palmer further stated, in relevant part:

> We continue to be driven by the possibility of bringing the first disease modifying therapy for T1D to market and look forward to continuing to work with the FDA during the regulatory process. ***Throughout the remainder of 2020, we plan to transition and transform our company into a commercialization ready organization in anticipation of the potential launch of teplizumab next year***.

82. The statements identified in Paragraphs 80 & 81 were materially false and misleading when made because the statements omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) there was significant risk that Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the teplizumab BLA; (ii) Provention's pivotal study did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol; (iii) the safety data for teplizumab was insufficient because it was unclear what happened to study participants who got Type 1 diabetes after being treated; (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (v) Provention's manufacturing facilities for teplizumab were deficient; (vi) consequently, the teplizumab BLA was deficient in its submitted

form and would require additional data to meet the standards for secure FDA approval; (vii) the teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed; and (viii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

83. Provention filed its Form 10-Q the same day, which the Individual Defendants signed pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"). The Form 10-Q discusses a number risk factors for Provention. Nowhere in the discussion of risk factors do Defendants acknowledge the Bridging Study, its importance to the teplizumab BLA, or the risk that a negative result from the Bridging Study might have on FDA approval. Instead, Provention's Form 10-Q simply offered vague platitudes, such as that it may not be able to ***"successfully start and complete clinical trials and obtain regulatory approval for the marketing of [Provention's] product candidates."*** Such statements were materially false and misleading when made because (i) there was significant risk that Provention's Bridging Study would fail to show PK comparability, thereby seriously compromising the teplizumab BLA; (ii) Provention's pivotal study did not meet its enrollment goal and only ended up testing the medication on 44 patients as opposed to the 71 patients called for by the trial protocol; (iii) the safety data for teplizumab was insufficient; (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a

multi-year delay in T1D, and which patients were at risk for safety concerns; (v) Provention's manufacturing facilities for teplizumab were deficient; and (vi) as a result, the prospective "risks" identified by Defendants had already materialized or were in the process of materializing.

84. Defendants also stated, in relevant part:

> ***In June 2020, extended follow-up data from the At-Risk Study was announced which showed that a single 14-day course of teplizumab significantly delayed the onset of T1D in At-Risk patients by a median of approximately three years compared to the placebo.*** This data added one year to the two-year median delay that was previously reported at the American Diabetes Association meeting in June 2019 and published in the New England Journal of Medicine

85. Defendants further stated that, "***[i]n summary, while no additional safety signals have been noted, the results showed that teplizumab's effect on delaying the onset of clinical T1D was not only consistent from previous analyses, but was durable and now extended to a median of at least three years***."

86. The statements identified in Paragraphs 84 & 85 were materially false and misleading when made because the statements omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) there was significant risk that Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the teplizumab BLA; (ii) Provention's pivotal

study did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol; (iii) the safety data for teplizumab was insufficient because it was unclear what happened to study participants who got Type 1 diabetes after being treated; (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (v) Provention's manufacturing facilities for teplizumab were deficient; (vi) consequently, the teplizumab BLA was deficient in its submitted form and would require additional data to meet the standards for secure FDA approval; (vii) the teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed; and (viii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

87. Notably, analysts covering Provention interpreted the flurry of announcements in early November 2020 as a strong indication that Provention had "cover[ed] all their bases" and teplizumab would be approved by the FDA in 2021. *See* Alethia Young, Emma Nealon, Emily Bodnar, & Li Watsek, *3Q Update: Filing is in and we see a transformative 2021 on the way*, CANTOR FITZGERALD, November 5, 2020, at 1; *see also* Justin Kim, Hartaj Singh, & Yichuan Yan, *3Q20 Review: Teplizumab's Regulatory Path to Approval Stays Focus*, OPPENHEIMER & CO INC.,

November 5, 2020, at 1 (viewing BLA acceptance is a "key potential milestone" and noting that Oppenheimer's base case assumption is that teplizumab will be FDA-approved in mid-2021); David T. Hoang & Tong Liu, *3Q20: Pre-Commercial Activities Paving the Way for Teplizumab Launch in 2H21*, SMBC NIKKO SECURITIES AMERICA, INC., November 6, 2020, at 1 ("We, as well as management, expect for an FDA AdCom to be convened but do not anticipate this will be a hurdle on the way to a mid-2021 approval.").

88. On November 18, 2020, Provention participated in the Stifel Virtual Healthcare Conference where Palmer spoke about Provention's recently submitted BLA for teplizumab:

> . . . . TN10 study follow on data were presented that showed the original 14-day course of teplizumab investigational therapy continued to significantly delay the onset of T1D in study participants by a median of approximately three years compared to placebo, adding one more year to the previous two year median delay. ***Not only are the results of the TN10 study highly statistically significant with the p value of 0.006 tied to the original two year medium delay, they are also highly clinically relevant.***
>
> We're not talking about a delay of three days or three weeks or three months, all of which would be precious for any T1D patient and their families. It's a delay of approximately three years. There were even some patients receiving teplizumab who were still T1D-free after 8.5 years.

89. Palmer also stated that –

> As afforded by the breakthrough therapy designation, ***Provention has expressly requested a priority review, which means FDA's goal is to take action on our application within six months as compared to 10***

> ***months under standard review. Looking beyond to U.S. approval of teplizumab in the at-risk indication***, we are continuing to prepare the submission of our marketing authorization application or MAA to the European Medicines Agency in 2021.
>
> ***We have successfully completed the transfer of teplizumab's prior commercial scale manufacturing process from Eli Lilly's manufacturing facility in Ireland to Provention's contract manufacturing partner AGC Biologics in Seattle. Having successfully completed an engineering run at the end of last year and a CG GMP run in Q1 of this year, in August, we reported the unscheduled completion of our drug substance PPQ manufacturing campaign. PPQ stands for process, performance and qualification and consists of three back-to-back commercial scale runs required for the validation of our drug substance manufacturing process and the demonstration of our ability to manufacture consistently batch-to-batch at commercial scale. Results from these runs served as the foundation for our BLA's CMC module***.

90. The statements identified in Paragraphs 88 & 89 were materially false and misleading when made because the statements omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (ii) there was significant risk that Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the teplizumab BLA; (iii) Provention's pivotal study did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol; (iv) the safety data for teplizumab was insufficient because it was unclear what happened to study participants who got Type 1 diabetes after being

treated; (v) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (vi) Provention's manufacturing facilities for teplizumab were deficient; (vii) consequently, the teplizumab BLA was deficient in its submitted form and would require additional data to meet the standards for secure FDA approval; (viii) the teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed; and (ix) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

91. Provention also took meetings with analysts after it submitted the teplizumab BLA to promote its efforts. For example, on December 10, 2020, Provention met with analysts from Cantor Fitzgerald. After its sit-down with the Company, Cantor Fitzgerald wrote an analyst report that highlighted its belief that teplizumab would receive FDA approval in mid-2021 and that "[m]anagement noted that they expect an advisory committee … and that [Provention] would be ready for one if need be." Alethia Young, Emma Nealon, Emily Bodnar, & Li Watsek, *Our takes from the NDR – we think PRVB is shaping up well for potential teplizumab approval in mid-2021*, CANTOR FITZGERALD, December 11, 2020, at 1.

92. On January 4, 2021, Provention put out a press release to announce that the FDA had officially filed the teplizumab BLA and granted Provention's request

for Priority Review with an advisory committee meeting scheduled for May 27, 2021 and a PDUFA date of July 2, 2021. The press release also quoted Palmer, who stated:

> The FDA's acceptance of our BLA represents a significant achievement for Provention Bio in our mission to deliver the first potential disease-modifying T1D therapy and drive a paradigm shift in how individuals at risk of developing the disease are treated[.] ***We intend to work closely with the FDA to support their review while also preparing for a potential product launch in the third quarter of 2021***.

93. The statements identified in Paragraph 92 were materially false and misleading when made because the statements omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) there was significant risk that Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the teplizumab BLA; (ii) Provention's pivotal study did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol; (iii) the safety data for teplizumab was insufficient because it was unclear what happened to study participants who got Type 1 diabetes after being treated; (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (v) Provention's manufacturing facilities for teplizumab were deficient; (vi) consequently, the teplizumab BLA was deficient in its submitted

form and would require additional data to meet the standards for secure FDA approval; (vii) the teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed; and (viii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

94. Analysts at the time interpreted this press release as a strong indication of FDA approval. *See* Alethia Young, Emma Nealon, Emily Bodnar, & Li Watsek, *FDA accepts BLA for Teplizumab with PDUFA of July 2; we still see upside over 2021*, CANTOR FITZGERALD, January 4, 2021, at 1 ("We think that Provention Bio remains a story underappreciated by investors … Management has previously commented that they expect to have an AdCom and would be ready for one if needed. We would expect a positive outcome in the AdCom given teplizumab has shown an ability to delay or prevent type 1 diabetes by a median of three years compared to placebo"); Gregory Renza & Yinglu Zhang, *Teplizumab's Path in 2021 Now Set with Priority Review; May Adcom, July PDUFA Come into Focus*, RBC CAPITAL MARKETS, LLC, January 4, 2021, at 1 ("We remain encouraged by the consistent progress made by PRVB on the BLA filing of teplizumab, and look to the AdComm for more insight into the approval potential, and even program debate, though we remain confident based on the strong clinical data, as well as the payer/market research and infrastructure preparations that the company is focusing

on - led by the first mass screening program for early-stage T1D launched by JDRF in December 2020 - we believe the approval of teplizumab in at-risk T1D holds disruptor potential within the T1D insulin market"); Raghuram Selvaraju, *Teplizumab Application Accepted for Review; Reiterate Buy*, H.C. WAINWRIGHT & CO. EQUITY RESEARCH, January 5, 2021, at 1 ("We anticipate that the advisory committee vote should be solidly in favor of approval for teplizumab, given the strong efficacy data demonstrating the drug's ability to modify the course of disease and even prevent onset of disease in T1D patients.").

95. The stock market was equally bullish with Provention on the heels of its January 4th announcement, and Provention's stock price rose by $1.32, or 7.79%, from $16.94 on December 31, 2020 to close at $18.26 on January 4, 2021.

96. Analysts continued to promote Provention and teplizumab's inevitable FDA approval throughout January and into February 2021, ***having been given no indication that there were any issues or risks with teplizumab's BLA***.

97. For example, on January 11, 2021, Provention participated in the H.C. Wainwright BioConnect Conference, where the moderator prefaced a question to Palmer about pre-commercial preparations for teplizumab with, ***"we should have an approval decision on or around July 2 of this year. And especially given the extremely convincing nature of the At Risk Study data, I think we can all agree that the advisory committee meeting should go well."*** Analyst reports at the time

echoed this sentiment, giving investors no indication that anything was amiss. *See* Raghuram Selvaraju, *PRV-3279 Preclinical Data Released; Cash Replenished; Reiterate Buy*, H.C. WAINWRIGHT & CO. EQUITY RESEARCH, January 29, 2021, at 1 ("We anticipate that the advisory committee vote should be solidly in favor of approval for teplizumab, given the strong efficacy data demonstrating the drug's ability to modify the course of disease and even prevent onset of disease in T1D patients.").

VI. The Results of the Bridging Study Begin to be Revealed

98. On January 12, 2021, Provention conducted a stock offering of 6,000,000 shares of common stock. In its offering form, it discussed, for the first time, results of the Bridging Study as a "risk factor," even though the "risk" was a question of present fact. Provention, however, failed to provide a full report to investors of its Bridging Study and how the PRVB-teplizumab's AUC was significantly lower—indeed, outside of the 80%-125% range—than the Lilly-teplizumab's AUC, and instead stated:

> ***We believe, based on the data and our analysis, that the results of the PK/PD bridging study suggest that the drug substances manufactured by AGC Biologics and Eli Lilly are comparable. Comparison of drug plasma concentration versus time after dosing shows a lower area under the curve, or AUC, for the PRV-031 drug product derived from the drug substance manufactured by AGC Biologics. Based on our PK/PD modeling, we do not believe this lower AUC is significant enough to impact the efficacy or safety of the to-be-commercialized PRV-031 drug product when used as proposed in our BLA filing. We submitted our finalized Clinical Study Report and discussion***

> ***document to the FDA in January 2021. The FDA could disagree with our analysis and interpretation of the PK/PD bridging study, including with respect to the observed lower AUC, and, as a result, could require additional analyses and modeling, or additional information from ongoing or new studies to support the commercial use of the PRV-031 drug product derived from the drug substance manufactured by AGC Biologics.***

99. The statements identified in Paragraph 98 were materially false and misleading when made because the statements omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the teplizumab BLA; (ii) Provention's pivotal study did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol; (iii) the safety data for teplizumab was insufficient because it was unclear what happened to study participants who got Type 1 diabetes after being treated; (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (v) Provention's manufacturing facilities for teplizumab were deficient; (vi) consequently, the teplizumab BLA was deficient in its submitted form and would require additional data to meet the standards for secure FDA approval; (vii) the

teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed; and (viii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

100. Despite Provention's spin, on the day after Provention's partial disclosure, its stock dropped by $2.79, or 14.34%, from $19.45 on January 12, 2021 to close at $16.66 on January 13, 2021.

101. On February 25, 2021, Provention filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2020 (the "2020 10-K"). The 2020 10-K touted the Company's teplizumab BLA submission, stating, in relevant part:

> ***We believe, based on the data and our analysis, that the results of the PK/PD study suggest that the drug substances manufactured by AGC Biologics and Eli Lilly are comparable. Comparison of drug plasma concentration versus time after dosing shows a lower AUC, for the teplizumab drug product derived from the drug substance manufactured by AGC Biologics. Based on our PK/PD modeling, we do not believe this lower AUC is significant enough to clinically impact the efficacy or safety of the to-be-commercialized teplizumab drug product when used as proposed in our BLA filing. At our February 2021 mid-cycle review meeting with FDA, among other matters, we addressed various questions and preliminary concerns raised by FDA relating to the PK/PD study results and our conclusions, including that we believe study results support PD comparability and that our modeling supports that the lower PK AUC, which potentially indicates that the drug substance manufactured by AGC Biologics may have cleared faster from the blood stream than the drug substance manufactured by Eli Lilly, should not impact safety or efficacy in a clinically meaningful way.*** At the meeting, FDA indicated that they will be providing us with various additional information requests which we plan to address promptly after receipt. The FDA stated it could not comment on a resolution to its concerns relating to the PK/PD study results at the meeting.

> Ultimately, there is no guarantee that the FDA will agree with our analysis and interpretation of the PK/PD bridging study, including with respect to the observed lower AUC and, as a result, the agency could require additional analyses and modeling, or additional information from ongoing or new studies to support the commercial use of the teplizumab drug product derived from the drug substance manufactured by AGC Biologics. ***If we are unable to satisfy the FDA's comparability requirements***, the timing of the FDA's review and decision on the teplizumab BLA could be delayed, or its approvability negatively impacted, including the potential issuance of a complete response letter, which would have a material adverse impact on our business.

102. Defendants also stated that "***[i]n June 2020, extended follow-up data from the at-risk study was announced which showed that a single 14-day course of teplizumab significantly delayed the median onset of T1D in at-risk individuals of approximately three years compared to the placebo***."

103. Appended to the 2020 10-K as exhibits were signed certifications pursuant to SOX by the Individual Defendants, attesting that "the information contained in the [2020 10-K] fairly presents, in all material respects, the financial condition and results of operations of Provention Bio."

104. The statements identified in Paragraphs 101-103 were materially false and misleading when made because the statements omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the

teplizumab BLA; (ii) Provention's pivotal study did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol; (iii) the safety data for teplizumab was insufficient because it was unclear what happened to study participants who got Type 1 diabetes after being treated; (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (v) Provention's manufacturing facilities for teplizumab were deficient; (vi) consequently, the teplizumab BLA was deficient in its submitted form and would require additional data to meet the standards for secure FDA approval; (vii) the teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed; and (viii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

105. Buried within Provention's 10-K was the partial disclosure that the Bridging Study had revealed:

> Comparison of drug plasma concentration versus time after dosing ***shows a lower AUC, for the teplizumab drug product derived from the drug substance manufactured by AGC Biologics***.

106. Provention further conceded that, in a mid-February 2021 meeting the with FDA, it addressed questions related to the Bridging Study results and that the

FDA "could not comment on a resolution to its concerns relating to the [Bridging Study] results at the meeting."

107. However, Provention was quick to counter any narrative that the Bridging Study results would be impactful on teplizumab's BLA, thus continuing Defendants' deception, and stated that it believed, ***"based on the data and [Provention's] analysis, that the results of the [Bridging Study] suggest that the drug substances manufactured by AGC Biologics and Eli Lilly are comparable."*** Further, it noted that, "***[b]ased on [Provention's] PK/PD modeling, [Provention does] not believe this lower AUC is significant enough to clinically impact the efficacy or safety of the to-be-commercialized teplizumab drug product when used as proposed in [Provention's] BLA filing."***

108. The statements identified in Paragraph 107 were materially false and misleading when made because the statements omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the teplizumab BLA; (ii) Provention's pivotal study did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol; (iii) the safety

data for teplizumab was insufficient because it was unclear what happened to study participants who got Type 1 diabetes after being treated; (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (v) consequently, the teplizumab BLA was deficient in its submitted form and would require additional data to meet the standards for secure FDA approval; (vi) the teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed; and (vii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

109. Concurrent with its 2020 10-K, Provention issued a press release on February 25, 2021, announcing the Company's Q4 and full year 2020 financial results and providing a business update. Notably, the press release omitted any reference to the Bridging Study or mounting FDA concerns about PK comparability. The press release stated, in relevant part:

> "2020 was a pivotal year for Provention Bio and the type 1 diabetes (T1D) landscape," stated Ashleigh Palmer, CEO of Provention Bio. "***The FDA's filing of our BLA for teplizumab represents a momentous achievement for Provention Bio in our mission to potentially deliver the first disease-modifying T1D therapy, which may catalyze a paradigm shift in how pre-symptomatic, at-risk patients are screened and treated before the clinical diagnosis of T1D. We look forward to working closely with the FDA to support the Agency's Priority Review, while we prepare for a potential commercial launch in the second half of this year***."

110. The statements identified in Paragraph 109 were materially false and misleading when made because (i) the Priority Review sought by Provention was irrelevant to whether the teplizumab BLA would be approved; (ii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab; and (iii) Provention's manufacturing facilities for teplizumab were deficient, thereby hampering the prospects for a commercial launch.

111. That same day, Provention hosted an earnings call with investors and analysts to discuss the Company's Q4 and full year 2020 results (the "Q4 2020 Earnings Call"). During the scripted portion of the Q4 2020 Earnings Call, Palmer addressed, for the first time, comparability between the Lilly-teplizumab and the PRVB-teplizumab. Specifically, Palmer expanded upon the partial-disclosure Provention made in its 10-K by admitting that the Bridging Study demonstrated that the AUC for the PRVB-teplizumab was less than the Lilly-teplizumab after a single dose and that the PRVB-teplizumab fell outside of the FDA's 80-125% comparability target range of the Lilly-teplizumab—a conclusion that was shared with the FDA earlier in the month. Palmer addressed these results by stating:

> ***[t]he momentum we accelerated throughout 2020 continues to be driven forward into 2021 . . . .***
>
> ***
>
> The second regulatory reconsideration I would like to address pertains to comparability between drug product previously produced from Eli Lilly drug substance and that produced from our current manufacturing

partner AGC Biologics. ***We believe our assessment of the physio-chemical analyses of the two drug products which we submitted to the FDA in our CMC module demonstrates these drug products to be comparable. This assessment is also supported by the comparability in PD parameters evaluated in the PK/PD bridging study we conducted in healthy volunteers last year***.

However, ***the single administration low dose study also showed a slightly lower than target PK area under the curve for the AGC product indicating that in that particular study, the AGC product may have cleared faster from the bloodstream than the Lilly product. Based on our understanding of the relevant data and the extensive modeling we have conducted to date, we do not believe this observation will have a clinically relevant impact on either the safety or efficacy of the AGC product.***

As many of you know, we had our BLA mid cycle review meeting earlier this month ***and we had an opportunity to discuss this topic for the first time with the FDA and share our points of view regarding the interpretation of the data we have submitted. The FDA is still evaluating the PK/PD bridging study and will be conducting its own PK modeling to validate our conclusion.***

As a result of our Breakthrough Therapy designation for the at-risk indication, we continue to enjoy the benefit of frequent constructive and valuable dialogue with the agency on all aspects of our BLA filing and the preparations for our advisory committee meeting in May. Considering the teplizumab potentially represents the first disease-modifying therapeutic advance for T1D in over a century and given the substantial unmet need that remains for these patients and their families, ***we look forward to continuing to support the agency in its review of our BLA to be able to bring this innovative breakthrough therapy to patients later this year.***

112. In addition, when asked a question regarding product comparability, Palmer responded, in relevant part:

Q – Gregory Renza

Congratulations on the progress. Thanks for taking my question. Ashleigh, just wanted to follow up a bit on those FDA interactions to date and just in regards to the color on the mid-cycle review which are going to appreciate, just curious if you could just layer in perhaps your expectations around the comparability, timelines that the FDA is engaging into to do their own work there, and what elements you use to sort of arrive that I mean you're positioning about its current comparability? Thank you.

A – Ashleigh Palmer

[. . .] ***what we're dealing with in terms of the comparability is a very comprehensive panel of physiochemical analyses that released the product from the manufacturing site within specification and from a validated process now at AGC Biologics and comparing that to the specifications with regard to the Lilly substance manufactured a decade ago.***

And in that context the products are comparable. That is our assessment, that is our belief, and we believe that the agency will see that also. We then had a situation as you may recall where we started the PROTECT study with Lilly manufactured product and obviously have to transition to the AGC Biologics' product. And we did a single-dose study in healthy volunteers at a low dose because we obviously couldn't administer a full 14-day therapeutic dose to healthy individuals.

And we wanted to bridge to the new material in our PROTECT study. ***As a result of that single dose PK/PD bridging study again, all of the parameters were within anticipated target, especially the PD parameters which are more indicative of the efficacy in the safety with the exception of this AUC PK area under the curve. And that the AGC Biologics' sales were slightly below the target, indicating that it cleared a little faster.***

So what we have done in evaluating internally and in the submissions we've made to the agency is very extensive modeling which is very typical in the industry to show what the consequences of that would be and how the two products behave when you take into account 14 days at therapeutic dose.

> And from that analysis from that modeling, ***we do not believe that the difference in area under the curve will result in a clinically relevant difference in the safety and the efficacy of teplizumab***. And so that we've submitted to the agency the mid-cycle review meeting we had was the very first and only time to date that we had to discuss that, we laid out our results, our interpretation, and obviously they were not going to make a decision at that meeting. And they have indicated to us they will do their own modeling and we anticipate that they will make information requests in the coming week -- in the coming weeks in order to enable them to do a comparison between their modeling and our modeling, and whether they arrive at the same conclusion that we do. ***And we have confident in the interpretation that we have submitted to them***.

113. The statements identified in Paragraphs 111 & 112 were materially false and misleading when made because the statements omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the teplizumab BLA; (ii) Provention's pivotal study did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol; (iii) the safety data for teplizumab was insufficient because it was unclear what happened to study participants who got Type 1 diabetes after being treated; (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (v)

Provention's manufacturing facilities for teplizumab were deficient; (vi) consequently, the teplizumab BLA was deficient in its submitted form and would require additional data to meet the standards for secure FDA approval; (vii) the teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed; and (viii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

114. Provention also participated in the 10th Annual SVB Leerink Global Healthcare Conference on the same day and, in response to a question concerning biocompatibility and teplizumab's BLA, Palmer stated:

> **Q – Thomas Smith**
>
> Right, okay. Now that's great and --that all makes sense. Maybe one last question, just on the regulatory side of things and then I want to make sure that we get to the commercial and we get to some of the pipelines are. I guess -- what drives your level of comfort, you guys, you did change the manufacturing here and you've brought in AGC Biologics to do the manufacturing. What drives your confidence in regulatory approval for teplizumab without the need for any additional either biocompatibility or bridging study using the AGC Biologics products. You obviously had a very strong year of execution in 2020 on the manufacturing front. Just give us your sense of confidence as we approach the BLA.
>
> **A – Ashleigh Palmer**
>
> Yeah, no, it's a great question and obviously, ***the Lilly drug substance from which the original material was derived used in the TN10 was produced a decade ago by the process, so that wasn't validated and is no longer available. We have material that we've been able to compare the drug product from resulting from that process with the material that we have produced at AGC Biologics as a result of a***

technology transfer. And from a manufacturing point of view, the material is comparable.

If you look at all the Physio chemical tests that are done to release batches and so on, all the material that we have seen manufactured in the GMP run and that PPQ runs during the summer meets all of the determined specifications and from our perspective is comparable. Now, what we did as a result of knowing that our PROTECT study, which was extended obviously in duration due to the, due to the COVID pause that we had is going to have to have a mid a mid-study transition, if you like, from the Lilly product that started the study with the material that we produced at AGC Biologics. ***We did a PK-PD bridging study, it was not a study that we could do in patients administering 14 days of a therapeutic dose. We did it in healthy volunteers. It was taking blood samples over a very frequent stage is looking at blood levels and so on. From a low dose, a single dose in healthy volunteers. And again, that study from most aspects confirms in our mind the comparability of the material, especially the pharmacodynamic endpoints***.

However, there was one Pharmacokinetic component, which we refer to as the area under the curve, which you can essentially assume means what's the rate at which the material clears from the bloodstream, and that component in that particular study missed the target by an amount not terrifically sort of larger significant amount, but it fell below that target.

And so that suggests that the AGC Biologics materially in that study cleared a little faster from the bloodstream. What we then did and what we were going to do anyway from that bridging study is a lot of modeling to look at what does that mean when you administer the material at therapeutic doses in patients over 14 days and when we look at that modeling again, we believe that the material is comparable and we believe that there are no clinically relevant consequences from that AUC difference nothing with respect to safety and nothing with respect to efficacy and we presented that to the agency. They have an opportunity to see that for the first time just before the mid-cycle review, we discussed it with them there and they've told us that they want to do their own modeling. They want to validate our modeling and our assumptions are correct and that they

> ***may well have information requests for us in terms of interrogating that modeling and our conclusions and that's where we are at this point. But again, we believe that material is comparable***.

115. The statements identified in Paragraph 114 were materially false and misleading when made because the statements omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the teplizumab BLA; (ii) Provention's pivotal study did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol; (iii) the safety data for teplizumab was insufficient because it was unclear what happened to study participants who got Type 1 diabetes after being treated; (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (v) Provention's manufacturing facilities for teplizumab were deficient; (vi) consequently, the teplizumab BLA was deficient in its submitted form and would require additional data to meet the standards for secure FDA approval; (vii) the teplizumab BLA lacked the evidentiary support the Company had led investors to

believe it possessed; and (viii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

116. Analysts interpreted the flurry of announcements from Provention on February 25, 2021, as a positive sign for FDA approval and were convinced by Provention that any issues with biocompatibility would be addressed as a post-marketing commitment and would not present a hurdle to FDA approval. *See* Alethia Young, Emma Nealon, Emily Bodnar, & Li Watsek, *4Q Take: Progress continues toward expected July launch in Type 1 Diabetes (T1D)*, CANTOR FITZGERALD, February 25, 2021, at 1 ("We remain confident on PRVB having a positive teplizumab panel and approval … [a]s it relates to a companion diagnostic, we think it may be a post-marketing commitment"); David T. Hoang & Tong Liu, *FY20: Mid-Year Approval and 2H21 Launch Expected for Teplizumab in At-Risk T1D*, SMBC NIKKO SECURITIES AMERICA, INC., February 26, 2021, at 1 ("We caught up with mgmt.. after the earnings call and our confidence in high likelihood of a mid-year approval for teplizumab was reinforced. We believe the regulatory issues are minor, have no bearing on the drug's approvability, and can be addressed post-market.").

117. Nevertheless, despite the spin about the Bridging Study's results from Provention on the day of the partial disclosure about the Bridging Study and its impact on teplizumab's BLA, Provention's stock price dropped by $1.82, or 12.42%, from $14.65 on February 24, 2021 to close at $12.83 on February 25, 2021.

118. On March 3, 2021, Provention issued a press release to announce extended follow-up data from the TN-10 study that showed "that a single 14-day infusion course of teplizumab (PRV-031) delayed the onset of clinical disease and insulin dependence in at-risk type 1 diabetes (T1D) patients by approximately three years (median of 32.5 months), adding one year to previously reported results." The press release also quoted Palmer, who stated:

> "These data embolden our enthusiasm surrounding the potential impact teplizumab may have on the lives of T1D patients, families and caregivers," said Ashleigh Palmer, CEO and Co-Founder, Provention Bio. "***Outcomes such as these validate Provention's mission to intercept and prevent debilitating and life-threatening diseases. We continue working closely with the FDA in their review of our BLA submission for teplizumab. The PDUFA goal date is July 2, 2021."***

119. The statements identified in Paragraph 118 were materially false and misleading when made because the statements omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the teplizumab BLA; (ii) Provention's pivotal study did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol; (iii) the safety data for teplizumab was insufficient because it was unclear what happened to study

participants who got Type 1 diabetes after being treated; (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (v) Provention's manufacturing facilities for teplizumab were deficient; (vi) consequently, the teplizumab BLA was deficient in its submitted form and would require additional data to meet the standards for secure FDA approval; (vii) the teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed; and (viii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

120. Shortly after its March 3rd press release, Provention participated in the H.C. Wainwright Annual Global Life Sciences Virtual Conference on March 9, 2021, where it discussed the TN-10 follow-up data. In particular, Drechsler stated:

> The TN-10 study showed us that a single 14-day course of treatment administered via IV 30 to 60 minutes per day produced a 32.5-month improvement in time to clinical onset for those who received treatment with teplizumab as compared to placebo. ***In fact, one subject has yet to develop clinical type 1 diabetes more than eight years after their initial receipt of teplizumab. These are remarkable results.***
>
> . . . .
>
> Teplizumab has been studied for several decades. Most common side effects noted in the TN-10 study were transient and were as expected based on the mechanism of action of teplizumab. ***There are over 800 patients that have been treated with teplizumab through its development lifecycle, and this represents a solid safety database for us.***

121. The statements identified in Paragraph ___ were materially false and misleading when made because (i) Provention's Bridging Study failed to show PK comparability; (ii) as Defendants later admitted, they had not yet conducted a full review of the PK/PD modeling; (iii) the safety data for teplizumab was insufficient; (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (v) consequently, the teplizumab BLA was deficient in its submitted form and would certainly require additional data to secure FDA approval; and (vi) the teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed. (i) Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the teplizumab BLA; (ii) Provention's pivotal study did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol; (iii) the safety data for teplizumab was insufficient because it was unclear what happened to study participants who got Type 1 diabetes after being treated; (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (v) Provention's manufacturing facilities for teplizumab were deficient, and therefore the manufacturing submission

was not "robust"; (vi) consequently, the teplizumab BLA was deficient in its submitted form and would require additional data to meet the standards for secure FDA approval; (vii) the teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed; and (viii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

122. On March 16, 2021, Provention participated in the Oppenheimer 31st Annual Healthcare Conference, where the moderator questioned Palmer about biocompatibility and questions being raised about the Bridging Study:

> **Q – Justin Kim**
>
> . . . . With investors we've spoken with, a key focus has been on manufacturing and CMC and while those have to some extent been addressed with the CMC filing and ultimate commission for teplizumab, what the Company has noted that there has been some questions raised by the agency around that. And can you just sort of discuss with us what the state of those questions have been and sort of maybe the timing around where we may see more visibility on the subject?
>
> **A – Ashleigh Palmer**
>
> Yeah. Thank you for bringing that up. ***I think you're referring to the PK/PD which was really brought to the extension of investments through our risk factors in documents that we filed at the beginning of the year as opposed to questions that were raised because -- by the agency because we had only at that point just received our filing confirmation and PDUFA date. And whilst it's certainly connected to manufacturing, the manufacturing submission itself is very robust.***

. . . .

> ***However, we knew that we would have to complete the final stages of our PROTECT newly diagnosed study with the new material having started that study with the Lilly material. And so we did a single dose, low dose PK/PD study -- bridging study for that purpose in healthy volunteers. And when we looked at all of the parameters coming out of that study, especially the PD parameters and so on, we also saw comparability reinforcing our assessment for manufacturing. But there was one PK parameter, the area under the curve, which is really suggesting the rate at which the material clears from the blood stream with the AGC product (inaudible) the original target range in that study and it suggested AGC product might clear a little faster.***
>
> Now because that was done in one dose, low dose in healthy volunteers, our ability to then determine whether that's relevant or not in the clinical setting and the therapeutic setting depends upon modeling. ***We did extensive modeling and when we submitted that study to our IND for the agency to look at, we included the modeling and that modeling in our estimation concludes the material is comparable and that any differences will not be clinically relevant when you scale up to therapeutic doses you administer it for 14 consecutive days in patients. And that's our conclusion.***

123. The statements identified in Paragraph 122 were materially false and misleading when made because the statements omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the teplizumab BLA; (ii) Provention's pivotal study did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol; (iii) the

prospective "risks" identified by Defendants had already materialized or were in the process of materializing. (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (v) Provention's manufacturing facilities for teplizumab were deficient; (vi) consequently, the teplizumab BLA was deficient in its submitted form and would require additional data to meet the standards for secure FDA approval; (vii) the teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed; and (viii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

124. Palmer then went further, in responding to the moderator's question about how best to address issues with biocompatibility, by outlining Provention's "wonderful relationship" with the FDA and how biocompatibility will not be a significant issue:

> **Q – Justin Kim**
>
> Understood. And so when we think about sort of potential late cycle review and serve an ultimate decision, do you have a sense that this could be addressed or you could get feedback on these points ahead of an ultimate decision for the filing or is that sort of the base case that the decision would sort of come in conjunction?
>
> **A – Ashleigh Palmer**
>
> ***Oh, we have a wonderful relationship with the agency. They have been incredibly supportive throughout the rolling submission and we***

> ***have a good open dialog with them and we anticipate a continuing discussion around this. And certainly that feedback is likely to come before a decision as is more questions or discussion around the modeling. We don't anticipate that this would be an Adcom issue because it really doesn't require input from patients or from clinical experts. It's really a technical assessment and we are hopeful that when the agency has had a chance to do its modeling and address all of its information requests that they have come to the same conclusion that we have***.

125. The statements identified in Paragraph 124 were materially false and misleading when made because the statements omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the teplizumab BLA; (ii) the internally-known Bridging Study failure to show compatibility would almost certainly be an issue at the Advisory Committee; and (iii) the FDA was highly unlikely to "come to the same conclusion" as Defendants regarding the teplizumab BLA.

126. Around the same time as Palmer's comments at the Oppenheimer 31st Annual Healthcare Conference, Provention spoke with analysts for SMBC Nikko Securities America, Inc. and assuaged them that the biocompatibility issue would not prevent FDA approval. *See* David T. Hoang & Tong Liu, *Incremental Data Points Reinforce Our Confidence in Approvability of Teplizumab*, SMBC NIKKO

SECURITIES AMERICA, INC., March 16, 2021, at 1 ("We remain confident that PRVB's PK modeling of a full 14-day dose schedule can assuage FDA concerns and expect to see KOL support voiced at the upcoming AdCom meeting on May 27th").

VII. The Truth Continues To Emerge

127. On April 8, 2021, Provention announced in a press release that the FDA had sent the Company a notification on April 2, 2021, stating that the FDA "has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time." More significantly, Provention also announced that during an informal discussion on April 2, 2021:

> [T]he FDA informed the Company that it had completed its review of the data and analysis submitted by the Company for its single, low-dose pharmacokinetic/pharmacodynamic (PK/PD) bridging study conducted in healthy volunteers. This study evaluated the PK/PD comparability of drug product originating from drug substance manufactured by AGC Biologics, which the Company plans to use for commercialization, and drug product originating from historic drug substance manufactured by Eli Lilly used for the TN-10 study submitted for the teplizumab BLA. ***The FDA indicated that based on the data it has reviewed to date, the Agency's position is that the PK profiles of the two drug products evaluated in the PK/PD bridging study were not comparable and that additional data would be required before the FDA's considerations could be satisfied.*** As a follow up, today, the FDA stated to the Company that it is willing to discuss these issues concurrently with its ongoing review. The FDA intends to continue the review of clinical data submitted in the BLA and to conduct the Advisory Committee meeting, scheduled on May 27, 2021.

128. On this news, Provention's stock price fell $1.73 per share, or 17.78%, from $9.73 on April 8, 2021 to close at $8.00 per share on April 9, 2021.

129. Analysts immediately noted the impact of the FDA's position on the Bridging Study and downgraded their price targets for Provention. *See* Justin Kim, Hartaj Singh, & Yichuan Yan, *Uncertainty and Deficiencies Reset Expectations for Teplizumab Timeline; PT to $18*, OPPENHEIMER & CO INC., April 9, 2021, at 1 (downgrading the price target for Provention from $29 to $18 per share); Alethia Young, Emma Nealon, Emily Bodnar, & Li Watsek, *FDA's request for additional PK data increases risk of delay but we remain confident in eventual approval*, CANTOR FITZGERALD, April 9, 2021, at 1 (downgrading the price target for Provention from $27 to $25 per share).

130. On April 27, 2021, Provention announced in a press release that participated in an informal meeting with the FDA on April 23, 2021, where ***the FDA reported at the meeting that it had concluded that the PK profiles of the Eli Lilly-teplizumab and the AGC-teplizumab evaluated in the Bridging Study are "not comparable, since the intended commercial product did not meet the pre-specified 80-125% PK area under the curve (AUC) comparability target range."*** The FDA also stated that it could not "be certain if this observation is not clinically relevant[.]" In response, Provention announced in its press release that "the FDA's PK comparability considerations are likely to result in a delay in potential BLA approval timelines and that the specifics of such delay will depend upon the outcome of ongoing discussions with the FDA to find a solution, including potentially providing

FDA reviewers with PK/PD data from the Company's on-going Phase 3 PROTECT study in newly diagnosed patients."

131. Provention's April 27th press release also announced that:

> The FDA also informed the Company that it plans to mention its PK comparability review in the clinical pharmacology summary of its briefing materials for the Advisory Committee meeting on May 27th, along with a statement that the FDA is actively working with the Company to resolve the issue and that the focus of the Advisory Committee meeting is efficacy and safety of teplizumab. It is the Company's understanding that since the FDA's PK comparability considerations do not bear on the benefit-risk assessment of the TN-10 study clinical data package, no comparability related questions or discussion topics are planned for the meeting. The FDA also recommended that both the FDA and the Company update their Advisory Committee briefing materials to reflect the removal of the term "prevention" from the previously proposed indication, as the remaining term "delay" more accurately reflects the results of the TN-10 trial.

132. Analysts responded to this news by noting that this news made "the July 2nd PDUFA date … very unlikely to be met." David T. Hoang & Tong Liu, *Still a Rocky Path Ahead for Teplizumab After Latest FDA Regulatory Update*, SMBC NIKKO SECURITIES AMERICA, INC., April 28, 2021, at 1.

133. On May 6, 2021, Provention held its Q1 2021 Earnings Call, where Palmer addressed teplizumab's BLA and the FDA's response to the Bridging Study in his prepared remarks:

> Before introducing new drug product containing AGC drug substance into our Phase 3 PROTECT trial in newly diagnosed T1D patients, we conducted a single low dose PK/PD bridging study in healthy volunteers and we observed a PK area under the curve or AUC level below the target

comparability range. Indicating that in this particular study, ***the new drug product might be clearing from the bloodstream faster than drug product manufactured from the old Lilly drug substance.*** Importantly, in this study, ***we believe that other relevant PK/PD parameters such as the peak concentration or Cmax, the clinically relevant PD marker of transient lymphocyte drop, the immunogenicity and the safety profile, all fell within acceptable ranges of comparability.***

As we stated previously based upon very extensive PK/PD modeling and taking into account the totality of the information available to us at this time, it is our firm belief that the observed difference in PKAUC is not clinically relevant and should not impact clinical efficacy or safety since the predicted exposure for the intended commercial product remains above the requisite threshold for beta cell protection. Based on its review to-date, the FDA is not comfortable with our conclusions. ***The agency has informed us that it does not yet consider the two drug products to be sufficiently comparable and cannot be certain that the PKAUC short-haul observed in our single low-dose PK/PD bridging study in healthy volunteers might not translate into clinical relevance.***

Nevertheless, under our breakthrough therapy designation, ***the FDA continues to be very engaged, very helpful and very cooperative and has agreed to work closely with us to figure out our next steps and the path forward to a solution, which we anticipate will likely require our provision of additional data to support PK/PD comparability***. One potential pathway maybe to access PK/PD data from patients in our ongoing PROTECT study, which has begun enrolling patients to receive either drug product drug product using the original Lilly drug substance or drug product intended for commercialization using AGC drug substance. We have also stated that we expect to need to provide the agency with additional data will result in a delay of the expected timelines within which teplizumab has the potential to be approved and made available to patients.

134. When asked by analysts about the AUC range and why comparability issues exist, Chief Scientific Officer Francisco Leon stated:

So the 80% to 125% is the target that is typically required for bioequivalence. Even though we are not obviously a biosimilar, we're

an innovative product it was used as a target as well in our study. ***As to why we were below that target, the honest answer is, we still don't know***. But this was a single low dose study in healthy volunteers. And we do believe that it bears no clinical relevance, especially when you think of multiple higher doses in patients, which is our intended use. So, we are working towards trying to understand it and also working towards providing additional data and analysis pharmacodynamic endpoints et cetera that might ameliorate FDA's questions and concerns.

135. Analysts followed up and pressed Provention as to why the comparability issue came up now, as opposed to eight months ago, to which Palmer responded that the Bridging Study results only "became available at the beginning of the year":

Q – Alethia Young

Just as a follow-up, so effectively, I guess it's kind of like maybe perhaps like you guys didn't think that the low-dose would be something that the FDA would be so focused on or I guess just I'm trying to figure out how it kind of all came together that it was now this like new focus in the past couple months universes, like, maybe like eight months ago.

A – Ashleigh Palmer

We conducted the PK/PD study specifically to bridge to the inclusion of the AGC, originated drug product in our PROTECT study. All of the physical-chemical analysis, and that includes assays, potency assays, and so on, conducted by AGC biologics and ourselves that were submitted into the BLA showed comparability as did many of the other parameters of the PK/PD study itself. ***The reason that it has appeared at the same time as the BLA is being reviewed is because that PK/PD studies result became available at the beginning of the year.*** And so the first time we had an opportunity to discuss this study, which has to be submitted to our IND and our BLA, we can't -- not disclose that to the agency was at the mid-cycle review in February and at that time

> they had indicated to us that they were evaluating the results and doing their own modeling. And as you know it was only in last month, April that we had meetings with the agency that indicated their conclusions that they were not comfortable with the comparability and that's where we're at today.

136. Palmer also conceded that the Bridging Study results would likely delay FDA approval:

> **A – David Hoang**
>
> Hi, guys. Thanks for the update and taking my questions. So I just had one on the -- one and then a follow-up. First one on the PDUFA date, July 2, we know it still stands. If that's just need to be revised or move, is that something that you're going to wait for the agency to give you that guidance? Or is that something you can have active conversation around?
>
> **A – Ashleigh Palmer**
>
> ***Well, we've indicated that there is likely to be a delay based on our understanding of the agency's position on comparability, we've not had discussions on how that delay will manifest itself whether it will be within the current review cycle with some extension or after a formal response. But we certainly indicated the potential for that delay.*** I think a lot will depend on the Adcom and the outcome of the Adcom and I suspect that the agency will wait until the Adcom has taken place, complete its clinical review. Take into consideration the meetings that we hope to have with them concurrently in regards to additional data we can provide and then we will obviously update you at the appropriate time when we have material information.

137. Provention also filed its Form 10-Q that same day, and breathlessly claimed that "***[o]ur rolling BLA submission for teplizumab in the At-risk indication has been initiated and is currently on track to be finalized upon completion of the CMC module by the end of 2020***."

138. However, the Company also conceded that:

> ***[t]he potential approval of the teplizumab BLA is subject to satisfactorily addressing issues raised by the FDA including its conclusion that the drug pharmacokinetic profiles of the two drug products evaluated in our PK/PD bridging study for teplizumab are not comparable***. This may require further development activities and additional data and ***will likely affect the timing of the review of and decision by the FDA on our BLA submission***.

139. On this mixed news, Provention's stock price fell $0.43 per share, or 6.02%, from $7.14 on May 7, 2021 to close at $6.71 per share on May 10, 2021.

140. The statements identified in Paragraphs 136-138 were materially false and misleading when made because the statements omitted the following material information necessary to make the statements not misleading under the circumstances in which they were made: (i) Provention's Bridging Study had not shown PK comparability, thereby seriously compromising Provention's ability to utilize the TN-10 clinical trial as evidence supporting approval of its version of the teplizumab BLA; (ii) Provention's pivotal study did not meet the enrollment specified in the original protocol and only ended up testing the medication on 44 patients, as opposed to the 71 patients called for by the trial protocol; (iii) the safety data for teplizumab was insufficient because it was unclear what happened to study participants who got Type 1 diabetes after being treated; (iv) teplizumab's overall risk-benefit profile made it difficult to predict which patients would derive a multi-year delay in T1D, and which patients were at risk for safety concerns; (v)

Provention's manufacturing facilities for teplizumab were deficient (vi) consequently, the teplizumab BLA was deficient in its submitted form and would require additional data to meet the standards for secure FDA approval; (vii) the teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed; and (viii) the Company had overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab.

141. At this point, analysts began to sour on the possibility that Provention would obtain FDA approval by the previously set July 2nd deadline. *See* Gregory Renza & Yinglu Zhang, *1Q21: Regulatory Uncertainty Remains for the Teplizumab BLA with Key AdComm Next*, RBC CAPITAL MARKETS, LLC, May 6, 2021, at 1 ("Though it is encouraging that AdComm is continuing as scheduled, we do not see high likelihood of the comparability issue being addressed timely before the PDUFA date or in the scenario where a 3-month PDUFA date extension is given, and remain cautious on the implications from a negative regulatory outcome").

VIII. The FDA's May 27, 2021 Advisory Committee

142. On May 25, 2021, the FDA released the briefing documents for the May 27th Advisory Committee for teplizumab in Type 1 diabetes. The FDA's briefing documents directly addressed the Bridging Study issue ***and disclosed that the mean AUC for the PRVB-teplizumab was less than half (48.5%, 90% CI: 43.6 to 54.1) of the AUC of the Lilly-teplizumab – which was the teplizumab used in the primary***

efficacy study. The FDA also noted that the reason for the AUC disparity appears to be a faster clearance of the PRVB-teplizumab from the circulation and not any differences in the strengths of the two teplizumabs.

143. Analysts who reviewed the documents noted that, "***the PK comparability issue which has plagued the drug continues to persist***." David T. Hoang & Tong Liu, *Drug Comparability Issue Remain the Elephant in the Room for Teplizumab*, SMBC NIKKO SECURITIES AMERICA, INC., May 26, 2021, at 1.

144. On May 27, 2021, the FDA held its Endocrinologic and Metabolic Drugs Advisory Committee, where Provention presented teplizumab for review and answered questions from the FDA. While refraining from addressing the looming Bridging Study result, ***the Advisory Committee instead raised serious questions about the size and scope of the TN-10 study, including the fact that the TN-10 study did not meet its enrollment goal and only ended up testing the medication on 44 patients*** as opposed to the 71 patients called for by the trial protocol.[13] Moreover, the Advisory Committee raised questions about the fact that the study did not follow patients after their diabetes diagnosis, leaving a gap in knowledge about long term safety of the PRVB-teplizumab.[14] ***The Advisory Committee also noted***

[13] *See* Amirah Al Idrus, *Provention Bio brought back down to earth as FDA panel narrowly backs diabetes prevention drug*, FIERCE BIOTECH (May 27, 2021), https://www.fiercebiotech.com/biotech/fda-panel-narrowly-backs-provention-bio-s-diabetes-drug-10-7-vote.

[14] *Id*.

that Provention included data from other trials of teplizumab in a different indication—something that the Advisory Committee noted was not a relevant comparison.[15] Put succinctly by one of the Advisory Committee members, "***[t]he safety data are really insufficient—we don't know what happened to people who got Type 1 diabetes after being treated***."[16]

145. Ultimately, the FDA voted 10-7 in favor of teplizumab. Analysts viewed the vote as a negative development, as analysts and investors who followed Provention's public statements had "expected a near-unanimous positive vote." David T. Hoang & Tong Liu, *FDA AdCom Renders Positive But Surprisingly Mixed Vote for Teplizumab in T1D*, SMBC NIKKO SECURITIES AMERICA, INC., June 1, 2021, at 1. ***Analysts also noted that, in addition to the issue of PK comparability raised in the Bridging Study, the FDA also had concerns about the drug's "overall risk-benefit profile, noting difficulty of predicting which patients would derive a multi-year delay in T1D vs. safety concerns that were not seen in the pivotal TN-10 trial but were raised by older Eli Lilly (LLY) studies***." *Id.*

146. After the 10-7 vote was announced, Provention's stock price fell $3.07 per share, or 28.74%, from $10.68 on May 27, 2021 to close at $7.61 per share on May 28, 2021.

---

[15] *Id.*
[16] *Id.*

147. On June 3, 2021, Provention participated in the Jefferies 2021 Virtual Healthcare Conference where Palmer addressed, among other things, the FDA's 10-7 Advisory Committee vote and Provention strategy moving forward concerning the PK comparability issues raised in the Bridging Study:

> Last week, Provention Bio and the FDA each had an opportunity to present their case for teplizumab to the FDA's endocrinologic and metabolic drug advisory committee. This committee does not typically review breakthrough rare disease RED diseases or immunologic therapies as it is a custom to evaluating therapies targeting more prevalent metabolic and endocrine diseases like type 2 diabetes and osteoporosis usually requiring large phase 3 clinical trials. Despite this the committee voted 10 to 7 that the benefits of teplizumab outweigh the potential risks in support of approval to delay clinical stage T1D in at-risk patients. This both represents yet another significant step closer to teplizumab potential commercialization, although it is only one consideration FDA will be taking into account when reviewing our Teplizumab BLA. One of the most memorable aspects of last week's advisory committee was the active participation of T1D community constituents, with their submission of over 180 letters to the FDA website. As well as their poignant testimonies during the open public hearing of the advisory committee meeting itself.
>
> The courage and conviction shown by so many patients, family members and T1D provisions, sharing their personal stories and experiences was both humbling and or inspiring. And so clearly highlighted the devastating burden of living with type-1 diabetes, and the worry of those at risk of developing this disease. As many of you are aware, we plan to continue working closely with the FDA, which is the ultimate decision maker to addressed the agency's comparability considerations, with respect to the drug product intended for commercialization, given that the TN-10 study was conducted using teplizumab originating from Eli Lilly drug substance last manufactured over a decade ago.
>
> One possible solution we have offered and are discussing with the agency is to provide the FDA with pharmacokinetic, and

> pharmacodynamic comparability data from a sub-study in our ongoing Phase 3 protect trial in newly diagnosed patients. And we hope to make progress with the agency in this regard and update you accordingly on the outcome. If the teplizumab is approved, our initial commercial strategy at launch will focus on the subset of at-risk patients who are dialect familial relatives of known type 1 diabetics. We believe there are currently 200,000 stage two pre-symptomatic T1D patients in the United States with to autoantibodies and dislikes senior of which 15% or roughly 30,000 patients are direct relatives of insulin-dependent type 1 diabetics.

148. On this news, Provention's stock price fell $0.26 per share, or 3.60%, from $7.21 on June 2, 2021 to close at $6.95 per share on June 3, 2021.

149. On July 6, 2021, Provention announced that it had received a CRL from the FDA on July 2, 2021. According to Defendants, ***the CRL stated that the FDA had concluded that the Bridging Study failed to show PK comparability, stating, "[a]s PK remains the primary endpoint for demonstration of comparability between the two products, you will need to establish PK comparability appropriately between the intended commercial product and the clinical trial product or provide other data that adequately justify why PK comparability is not necessary."*** Provention responded to the news of the CRL by stating:

> The Company expects relevant additional PK/PD data being, or to be, collected from a PK/PD substudy in patients receiving 12-days of therapy in the ongoing Phase 3 PROTECT trial in newly diagnosed T1D patients later this quarter. These data will be analyzed by independent, unblinded third-parties to maintain the integrity of this placebo-controlled trial. Upon review of the results from this substudy, the Company will determine whether to submit these data to the FDA for its review, along with any other relevant data and analyses based on

> our ongoing discussions with FDA, to support PK comparability or otherwise justify why PK comparability is not necessary.

150. Defendants further stated that ***the FDA noted that "certain deficiencies" with Provention's fill/finish manufacturing facility would need to be resolved before FDA approval***.

151. On this news, Provention's stock price fell $2.19 per share, or 26.38%, from $8.30 on July 2, 2021 to close at $6.11 per share on July 6, 2021, and again fell $0.12 per share, or 1.96%, to close at $5.99 per share on July 7, 2021. Within a two-day span, Provention's stock price fell $2.31, or 27.83%, from $8.30 to $5.99.

152. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

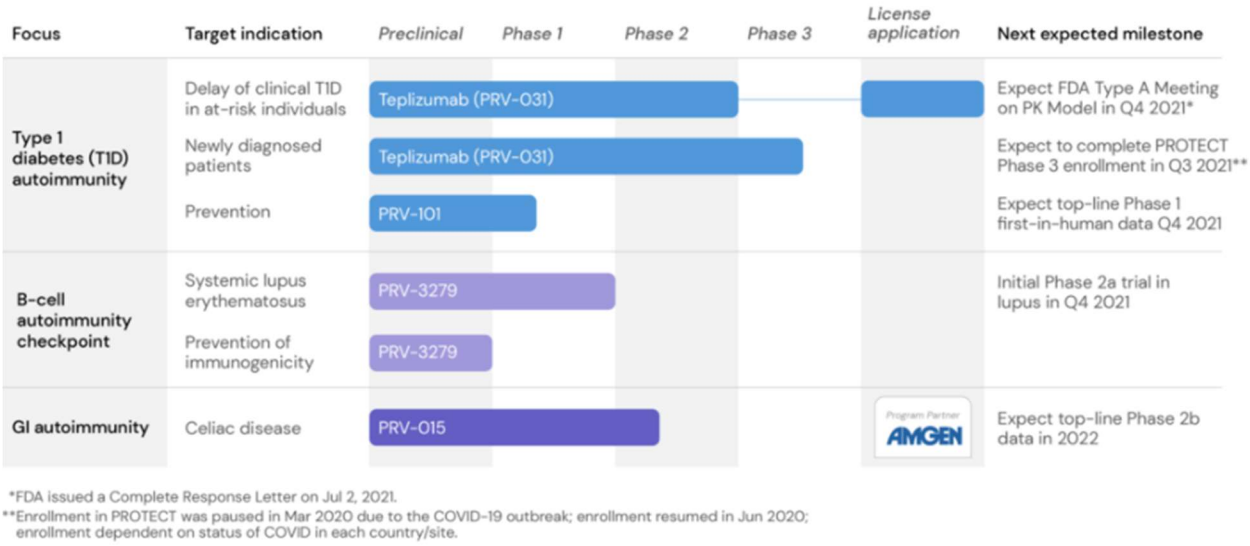
IX. Additional Allegations of Scienter

a. That Defendants' Misrepresentations Involved Provention's Core Operations Bolsters Scienter

153. Defendants' scienter is established because the alleged misstatements and omissions at issue here concerned Provention's core operations. Provention is a clinical-stage biopharmaceutical company that focuses on the development and commercialization of therapeutics and solutions to intercept and prevent immune-mediated diseases, including T1D. Since its acquisition in May 2018, teplizumab

has been its tentpole drug, with all other drugs in much earlier stages of development:[17]

154. Indeed, teplzumab was Provention's lead drug for its $56 million IPO filing in 2018.



155. Thus, it is inconceivable that Defendants would not know about the lack of PK comparability, the risks of the Bridging Study, the limitations of the TN-10 study, and other barriers to FDA approval of teplizumab's BLA.

b. That Defendants Held Themselves out as Knowledgeable About the FDA Bolsters Scienter

156. Defendants' own statements show that they repeatedly held themselves out as extremely knowledgeable about the regulatory landscape and in constant contact with the FDA. For example, on November 5, 2020, Palmer stated that

[17] Chart obtained from Provention's website. *See Change clinical practice*, PROVENTION BIO, INC., https://proventionbio.com/intercepting-autoimmune-disease (last accessed Dec. 22, 2021).

Provention, "look[s] forward to ***continuing to work with the FDA during the regulatory process***." Further, on January 4, 2021, Palmer stated, "[Provention] intend[s] to work closely with the FDA to support their review while also preparing for a potential product launch in the third quarter of 2021."

157. Given Defendants' own statements, it is inconceivable that Defendants would not know, or did not recklessly disregard, that their misleading statements throughout the Class Period misled investors.

c. That Defendants Have Extensive Experience in the Pharmaceutical Industry Bolsters Scienter

158. Palmer and Drechsler both have extensive experience in the pharmaceutical industry serving as high-level executives for multiple pharmaceutical companies. Through this experience, both Individual Defendants have experience shepherding drugs through the FDA approval process and communicating that information to investors. Consequently, both Palmer and Drechsler would have known the risks of the Bridging Study to FDA approval and the importance of conveying those risks—in full—to investors.

159. Thus, given Individual Defendants' experience, it is inconceivable that Palmer and Drechsler would not know, or did not recklessly disregard, that their misleading statements throughout the Class Period misled investors.

d. That Defendants Issued A Common Stock Offering in January 2021 Bolsters Scienter

160. As Provention was attempting to secure FDA approval for its PRVB-teplizumab, it also faced the reality of consistent operating losses and a potential cash-flow problem.

161. Provention incurred significant operating costs from 2019-2021 to support FDA approval and commercialization of PRVB-teplizumab. By its own admission in its November 5, 2020 10-Q, because Provention's most promising drug—and the only product it had close to market—was the PRVB-teplizumab, "[Provention] will operate at a loss for the foreseeable future or until such time as [Provention] obtain[s] regulatory approval for and execute a successful commercial launch of [PRVB-teplizumab], if ever."

162. Moreover, Provention was incurring significant losses from 2019 through 2021 and, because its most promising drug was not yet at market, was solely reliant on capital raises to stay afloat. Provention conceded this in its November 5, 2020 10Q when, discussing risk factors for its business, it stated:

> ***We need to raise additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate certain or all of our product development programs or commercialization efforts*** … For the nine months ended September 30, 2020 and 2019, we had a net loss of $66.0 million and $32.7 million, respectively, and as of September 30, 2020, we had an accumulated deficit of $145.1 million and $142.7 million in cash, cash equivalents and marketable securities.

163. On January 13, 2021, in line with its November 5, 2020 admission, Provention announced the pricing of its public offering of 6,250,000 shares of its common stock at a public offering price of $16.00 per share, with an expectation of earning $100 million in gross proceeds.

164. At the same time, Provention had learned that its Bridging Study found the PRVB-teplizumab's AUC to be outside the acceptable 80%-125% range of the Lilly-teplizumab, putting teplizumab's BLA in jeopardy. However, Defendants failed to convey the full extent of the Bridging Study results or its significance to the teplizumab BLA to investors during the January 13th offering. Had Defendants done so, investors would never have purchased Provention common stock at the inflated $16.00 per share price. Consequently, being so reliant on capital raises to keep Provention afloat, Defendants had a significant financial motivation to mislead investors about the flaws with its PRVB-teplizumab and the likelihood (or lack thereof) of FDA approval.

e. That The Individual Defendants Are Provention's Senior Executives Bolsters Scienter

165. Palmer and Drechsler had scienter as to the false and misleading nature of the statements described above because they were Provention's most senior executives and on its management team. As a result, Palmer and Drechsler knew facts or had access to information suggesting that their public statements were not accurate or failed to check the information they had a duty to monitor. In addition,

Provention's scienter can be inferred because the aforementioned statements would have been approved by corporate officials that knew that they were materially false or misleading.

f. That Defendants Palmer and Drechsler Certified Provention's 10-K Filing with the SEC Bolsters Scienter

166. Defendants Palmer and Drechsler's actual knowledge of the falsity of the alleged misstatements and omissions is also established by their signing of certifications in connection with Provention's filing of its Form 10-Ks with the SEC. These certifications certified, among other things, that the filing "fairly presents, in all material respects, the financial condition and results of operations of [Provention]." Before vouching for the accuracy of the statements made in Provention's filings, the certifying Individual Defendants were obligated to familiarize themselves with the contents of the filings and the underlying operations of Provention, including the relevant studies of its centerpiece drug, teplizumab, described therein.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

167. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Provention securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and

directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

168. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Provention securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Provention or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

169. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

170. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiffs has no interests antagonistic to or in conflict with those of the Class.

171. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations, and management of Provention;
- whether the Individual Defendants caused Provention to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Provention securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

172. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

173. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Provention securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiffs and members of the Class purchased, acquired, and/or sold Provention securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

174. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

175. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972),

as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

176. Plaintiffs repeat and reallege the allegations contained in Paragraphs 1 to 175 above, as if fully set forth herein.

177. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

178. During the Class Period, Defendants engaged in a plan, scheme, conspiracy, and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices, and courses of business which operated as a fraud and deceit upon Plaintiffs and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Provention securities; and (iii) cause Plaintiffs and other

members of the Class to purchase or otherwise acquire Provention securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants, and each of them, took the actions set forth herein.

179. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Provention securities. Such reports, filings, releases, and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Provention's finances and business prospects.

180. By virtue of their positions at Provention, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each

Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

181. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Provention, the Individual Defendants had knowledge of the details of Provention's internal affairs.

182. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Provention. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Provention's businesses, operations, future financial condition, and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases, and public statements, the market price of Provention securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Provention's business and financial condition which were concealed by Defendants, Plaintiffs and the other members of the Class purchased or otherwise acquired Provention securities at artificially inflated prices and relied upon the price of the securities, the integrity of

the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

183. During the Class Period, Provention securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued, or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Provention securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and the Class, the true value of Provention securities was substantially lower than the prices paid by Plaintiffs and the other members of the Class. The market price of Provention securities declined sharply upon the public disclosure of the facts alleged herein to the injury of Plaintiffs and Class members.

184. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

185. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with

their respective purchases, acquisitions, and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

186. Plaintiffs repeat and reallege the allegations contained in Paragraphs 1 to 175 above, as if fully set forth herein.

187. During the Class Period, the Individual Defendants participated in the operation and management of Provention, and conducted and participated, directly and indirectly, in the conduct of Provention's business affairs. Because of their senior positions, they knew the adverse non-public information about Provention's misstatement of income and expenses and false financial statements.

188. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Provention's financial condition and results of operations, and to correct promptly any public statements issued by Provention which had become materially false or misleading.

189. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases, and public filings which Provention disseminated in the

marketplace during the Class Period concerning Provention's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Provention to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Provention within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Provention securities.

190. Each of the Individual Defendants, therefore, acted as a controlling person of Provention. By reason of their senior management positions and/or being directors of Provention, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Provention to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Provention and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

191. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Provention.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

Dated: December 23, 2021

Respectfully submitted,

POMERANTZ LLP
/s/ Louis C. Ludwig

Joshua B. Silverman
Louis C. Ludwig
Christopher P.T. Tourek
POMERANTZ LLP
10 South LaSalle St., Ste. 3505
Chicago, Illinois 60603
Telephone: (312) 377-1181
Facsimile: (312) 377-1184
jbsilverman@pomlaw.com

lcludwig@pomlaw.com
ctourek@pomlaw.com

Jeremy A. Lieberman
J. Alexander Hood II
POMERANTZ LLP
600 Third Avenue
New York, New York 10016
Telephone: (212) 661-1100
Facsimile: (212) 661-8665
jalieberman@pomlaw.com
ahood@pomlaw.com

BRONSTEIN, GEWIRTZ & GROSSMAN, LLC
Peretz Bronstein
(*pro hac vice* application forthcoming)
60 East 42nd Street, Suite 4600
New York, New York 10165
Telephone: (212) 697-6484
Facsimile: (212) 697-7296
peretz@bgandg.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on December 23, 2021, a copy of the foregoing was filed electronically via the Court's CM/ECF system. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's CM/ECF System.

POMERANTZ LLP

By: */s/ Louis C. Ludwig*
Louis C. Ludwig

Lead Counsel